Follow-up to the European Parliament non-legislative resolution on the future of the EU biotechnology and biomanufacturing sector: leveraging research, boosting innovation and enhancing competitiveness

1. **Rapporteur:** Hildegard BENTELE (EPP / DE)

2. **References:** 2025/2008(INI) / A10-0123/2025 / P10_TA(2025)0165

3. **Date of adoption of the resolution:** 10 July 2025

4. **Competent Parliamentary Committee:** Committee on Industry, Research and Energy (ITRE)

5. **Brief analysis/assessment of the resolution and requests made in it:**

The resolution generally welcomes the EU Biotechnology and Biomanufacturing Communication and recognises the biotechnology and biomanufacturing sector as one of the 10 strategic sectors in the EU to boost Europe's competitiveness, economic security and sustainability.

The resolution also highlights the lengthy and complex authorization procedures which represents a competitive disadvantage for EU operators, the lack of an EU regulatory framework addressing the specificities of bio-based products, the need for an effective regulatory framework to conduct clinical research, and a specific attention to the safety and environment standards of non-EU countries.

The resolution also addresses the existing fragmentation of the investment and venture capital ecosystems which limits the ability of start-ups and small medium enterprises to scale-up and deploy technologies in a large scale, the inconsistency of the current EU regulatory frameworks across sectors which slows the market access of EU companies and the need to adequately address evolving risk and biosecurity gaps.

The resolution, among other elements:

- asks the Commission a new EU-wide regulation in the form of the EU Biotech Act and that its scope is cross-sectorial accompanied by an impact and cost assessment assessed by the Regulatory Scrutiny Board;

- asks the Commission to streamline the current approval procedure on clinical trials and calls for a swift implementation of the Clinical Trials Regulation and the use of the EU's Clinical Trials Information System;

- calls on the Commission to present an updated bioeconomy strategy which links to biotechnology and biomanufacturing and which incentivises the development and production of bio-based

products and contributes to the EU competitiveness and strategic autonomy;

- calls for an establishment of an EU biosecurity register, urges the Commission to conduct a study on biological materials and to present an updated communication and an action plan on chemical, biological, radiological and nuclear risks, in particular regarding bioterrorism and bio-risks;

- calls on the Commission to facilitate the creation of world-leading research hubs to drive innovation and collaboration between academia, industry and venture capital, and facilitate production and market access for SMEs and start-ups;

- asks the Commission to liaise with European Investment Bank (EIB) and calls EIB to propose derisking instruments for biotechnology;

- recalls the key role of framework programmes such as Horizon Europe in fostering scientific excellence, innovation and technical development and underlines the importance of leveraging public funding with private investment.

6. Response to requests and overview of actions taken, or intended to be taken, by the Commission:

In response to:

Paragraphs 1 and 5: The Commission acknowledges the growth potential of the European biotechnology and biomanufacturing sector as outlined in, among others, the Commission communication of 20 March 2024 entitled ‘Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU’ as well as in the report by Mario Draghi of 9 September 2024 entitled ‘The future of European competitiveness’.

The Commission undertook all necessary preparatory work for the EU Biotech Act I, including a call for evidence and a wide public consultation, in accordance with its Better Regulation rules. In view of the urgency to act in the area of health, the Commission is taking a two-staged approach. The Commission has proposed in December a first Biotech Act focused primarily on health-related biotech, streamlining EU rules and procedures to deliver solutions to patients and industry more quickly. The Biotech Act I also included provisional measures in the food and feed area and on biosecurity. The impact of the measures proposed will be provided in a staff working documents that will be adopted in the coming months. The Commission work programme 2026 announces a Biotech Act II which reaffirms biotechnology as a strategic technology across multiple sectors, essential for Europe's competitiveness, resilience, and clean and digital transitions. It will ensure a level playing field in the Single Market, eliminating fragmentation and guaranteeing that innovative biotech products and processes can quickly enter and freely circulate within the EU.

Stakeholders will have the opportunity to provide comments via the Call for Evidence, planned for publication in April. The Biotech Act II will be supported by an impact assessment to be submitted to the Regulatory Scrutiny Board.

Paragraph 2: So far, the Commission acknowledges the definition of biomanufacturing as stated in the Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU[1] as "the use and conversion of biotechnology and biological resources into chemicals, products and energy".

Paragraphs 3, 4, 6: The EU Life Sciences Strategy, is a comprehensive communication that adeptly addresses many of the critical issues raised by the Parliament on biotechnology and biomanufacturing. The strategy also declares a commitment to fully unlock the potential of biotech innovation in Europe; to do so it is important to assess current regulatory procedures, particularly for health and food applications, to make them more agile and proportionate, without compromising safety or scientific rigour.

In addition, the Commission acknowledged the need to streamline and harmonise the governance for Life Sciences, including biotechnology and biomanufacturing, within the Commission. For this purpose, an EU Life Sciences Coordination Group will ensure that various initiatives relevant to biotechnology and biomanufacturing, complement, synergise and do not contradict each other.

Paragraph 7: The regulatory frameworks of non-EU countries are tackled in the framework of the EU commercial policy. The EU free trade agreements with third countries promote the use of international and EU standards and provide a better level-playing field and a predictable business environment for EU companies going to international markets. In addition, strong provisions on intellectual property rights are also part of such deals, which provide for more stable and secured business. The Commission is committed to strengthening the competitiveness of the EU's biotechnology and biomanufacturing sectors while ensuring consumer, patient and environmental safety and to analyse all available evidence, including the experience of third countries in the areas of biotechnology and biomanufacturing when relevant.

Paragraph 8: The Commission has commissioned a study on regulatory challenges related to the placing on the market of products of biotechnology and biomanufacturing. The study will provide insights on the challenges and their causes and consequences that are encountered by public and private operators in the European single market in value chains involving biotechnology and/or biomanufacturing and that relate to the applicable EU and selected national legislation, their

[1] COM (2024) 137 final.

implementation or enforcement. A specific focus will lie on the identification of challenges that impede an efficient functioning of the European single market, that are resulting in unnecessary burden for operators or that disproportionately delay the market entry of a product/process of biotechnology and/or biomanufacturing. The study will further analyse the underlying reasons for some of the challenges and whether concrete provisions of the legislation, its implementation by the EU institutions and bodies and the Member States or its enforcement cause or contribute to the challenges identified. Based on the outcomes of the study and further sources of information, notably the calls for evidence and public consultations conducted in connection with the Biotech Act, A Strategic Framework for a Competitive and Sustainable EU Bioeconomy , the Startup and Scaleup Strategy, the Innovation Act, the EU Life Sciences Strategy and related Commission initiatives, the Commission will, where appropriate, bring forward legal proposals to simplify and streamline the legislation affecting products of biotechnology and biomanufacturing.

Paragraph 10 and 11: The Commission agrees with the need to explore how to simplify and accelerate certain authorisation procedures for biotechnology and biomanufacturing derived products, while at the same time maintaining the EU high level of safety standards for the protection of the EU citizens and the environment. Provisions in this sense have been included in the Biotech Act I proposed in December.

The Commission has already committed to adopting a number of legal proposals, including the Biotech Act II and the Innovation Act, as well as several sectoral simplification packages, to address identified shortcomings or excessive administrative burden resulting from current EU legislation impacting on biotechnology and biomanufacturing.

The Commission also recalls that an evaluation of the performance of the European Food Safety Authority (EFSA) is currently on-going. Based on the results of this evaluation, the Commission will also reflect on any necessary further improvements as regards the operation of EFSA. However, some provisions have already been addressed in the Biotech Act I proposal to remove the major bottlenecks for companies during the pre-submission phase of their dossiers and to improve EFSA’s efficiency.

In addition, the Commission published in November 2025 A Strategic Framework for a Competitive and Sustainable EU Bioeconomy, which announces the establishment of a European Bioeconomy Regulators and Innovators’ Forum to coordinate national and EU actions to fast-track authorisations for novel bio-based solutions and remove barriers.

Paragraph 12: The Commission acknowledges that relevant product labelling is essential for consumer information and safety; it is crucial in particular that all information needed by the consumers for purchasing decision and safety are available on the product. For additional information, alternative labelling practices are indeed considered and recommended, including the use of QR codes. The Empowering consumers for the green transition Directive provides for a notice and a label related to the legal guarantee of conformity and a commercial

guarantee of durability. The related implementing act proposes the use of QR codes in order to provide further non-essential information.

Paragraph 13: The Commission acknowledges that IP protection is essential for a thriving biotechnology sector. In addition to strong protection schemes, IP exploitation also plays a significant role: therefore, facilitating access to IP is essential to ensure optimal commercialisation and market uptake, as also highlighted in the Draghi report. The EU Biotech and Biomanufacturing Hub[2] compiles a range of resources, tools, and guidelines to help users to navigate IP protection and exploitation. The recently adopted Startup and Scaleup Strategy[3] highlights the issue of commercialisation of results in the section 'Fast market uptake and expansion'.

Paragraph 14 and 15: The EU Life Sciences Strategy places a strong emphasis on actions to streamline processes and create a more conducive environment for R&D and manufacturing in health-biotechnology. It explicitly prioritises clinical research competitiveness, committing to sustained implementation and monitoring of the Clinical Trials Regulation, including the continuous improvements of the Clinical Trials Information System (CTIS). It will enhance the attractiveness of the EU for clinical trials by reinforcing research infrastructures, promoting multi-country trials, and developing a dedicated investment plan for clinical research. It commits to fostering investments in innovative medicines such as advanced therapy medicinal products through the establishment of a network of Centres of Excellence as well as bioclusters, and partnerships, supporting both healthcare resilience and industrial competitiveness. Furthermore, a strong and competitive biotech sector is essential to develop and manufacture many of the medical countermeasures necessary to prepare for and respond to health emergencies. The Medical Countermeasures Strategy puts strong emphasis on stimulating and fostering innovation in this area.

The EU Biotech Act I has proposed amendments of the Clinical Trials Regulation, for instance to shorten the time to market for innovative medicinal products through regulatory simplifications and streamlining. This objective is to reduce administrative burdens and economic, social, and environmental costs, while enhancing the EU's long-term competitiveness, resilience, and strategic autonomy.

The Commission will continue investing in making the health and care sector more environmentally sustainable, including pharmaceutical production. It will closely monitor the progress of projects funded under the Horizon Europe "green pharma" cluster, which aim to enhance the sustainability of pharmaceutical products, as well as the PHARMECO project funded under the Innovative Health Initiative (IHI) JU. The latest will test how the Sustainable by design-driven technologies and processes perform at a larger scale, such as those needed for clinical

[2] Biotech and biomanufacturing - Your Europe.
[3] EU Startup and Scaleup Strategy - European Commission.

trials and transfer to standard manufacture settings. The ultimate objective is to accelerate the adoption of newly developed methods in both industry operations and in healthcare settings.

Paragraph 16 and 17: The Commission acknowledges the recommendation from the European Parliament to support companies moving from regulatory sandboxes to full market access. For instance: the EU's pharmaceutical reform proposes for the first time the possibility for regulatory sandboxes in the field of medicines. They provide a structured testing environment in which innovative methods and novel medicinal products can be tried out under the supervision of regulators. In addition, they offer an opportunity to learn not just about innovation, but also about the rules and regulations underpinning it and how they are best applied to future technologies. The learnings will be over time translated into adapted regulatory frameworks, thereby creating tailored horizontal rules that meet the required regulatory standards, while fully accommodating innovative elements.

In addition, the EU Life Sciences Strategy considers that future legislation should integrate experimentation clauses, derogations and the use of test environments such as regulatory sandboxes as was done for example in the proposed reform of the EU pharmaceutical legislation.

In the Strategic Framework for a Competitive and Sustainable EU Bioeconomy, the Commission announced that it will promote the use of test environments such as regulatory sandboxes in the bioeconomy, including in the context of the upcoming EU Innovation Act.

The Biotech Act proposed in December 2025 introduces the possibility to use regulatory sandboxes to trial innovation in a flexible but controlled environment in various areas: health, food and feed.

In the field of Health, the IHI JU recently launched a call for proposals to model regulatory sandbox mechanisms and methodologies and enable their deployment to support breakthrough innovation. The Commission plans to create an AI-powered interactive tool in 2026 to help researchers and innovators navigate the EU regulatory landscape, complementing the information available to companies through the Biotech and Biomanufacturing Hub particularly for the early stages of research and development.

Paragraph 18, 19, 20 and 21: The Commission adopted on 27 November 2025 A Strategic Framework for a Competitive and Sustainable EU Bioeconomy with a view to scale innovative, competitive bio-based products and services creating a level-playing field for lead bioeconomy materials (bio-based plastics and polymers, bio-based chemicals, bio-based construction products, textiles from bio-based fibres and fabrics, bio-based fertilisers and plant protection products) and for lead bioeconomy technologies (biorefineries, advanced fermentation, permanent storage of biogenic carbon). The Communication focuses on the challenges of the various sectors, and puts forward measures to reinforce bioeconomy's industrial dimension and its links to

biotechnology and biomanufacturing, for example by fostering the creation of new biomanufacturing demonstration infrastructure facilities through the Competitiveness Coordination Tool Pilot on the Bioeconomy, allowing start-ups and innovative companies to test the viability of new prototypes and products.). The strategy also considers the important role of biomass supply and use from land and water, the sustainability of bio-based solutions and the international dimension of the bioeconomy. Europe's biomass needs to be used efficiently by being directed towards higher value applications. Policy coherence and complementary of the various interconnected initiatives is key for all the sectors.

The Commission has no intention to propose or take any measures which would prohibit or disincentivise the use of enzymes, lactic acid bacteria or other microorganisms under chemicals legislation such as REACH.

Paragraph 22: The Commission would like to highlight that the European Investment Bank (EIB) Group Paris alignment framework and its interpretation remain the exclusive prerogative of the EIB groups and its respective Boards. The Commission may offer, if requested, its knowledge and experience stemming from relevant programmes and activities to contribute to biotechnology- and biomanufacturing friendly interpretations, in particular through the evolution of the policy to be conducted in the preparation of the Bank's new Climate Bank Roadmap 2026-2030. The current instruments provided by the EIB and the European Investment Fund (EIF), benefitting from the InvestEU Guarantee already provide de-risking for biotechnology and biomanufacturing projects with market potential directly though debt, venture debt, and indirectly through equity and guarantees. Initiatives such as HERA Invest provide for a dedicated window of the instruments for medical countermeasures development, responding to identified priorities such as pathogens with pandemic potential, antimicrobial resistance (AMR) as well as chemical, biological, radiological and nuclear (CBRN) threats. Such projects are also eligible for advisory support. There is close collaboration between the EIB Group and the Commission in outreach activities and information on financing instruments in particular for SMEs, start-ups and scale-ups.

Paragraph 23, and 24: The Commission agrees with the high potential and contribution of bio-based products and processes to the EU CO_2 reduction objectives, the need to demonstrate it via comprehensive life cycle assessments, as well as with the need to provide meaningful information to consumers. The Strategic Framework for a Competitive and Sustainable EU Bioeconomy addresses the need to support to sustainable bio-based products and better consumer information to stimulate demand for sustainable bio-based products and make them more competitive compared to fossil-based counterparts. The Competitiveness Coordination Tool (CCT) Pilot will support the creation of the 'Bio-based Europe Alliance' (BEA), a voluntary alliance of corporations that could ensure a reliable and predictable demand of biobased materials and products, reassuring private investors on their investments in CAPEX-intensive facilities as well as guaranteeing the

needed offtake agreements. In addition, the ongoing review of the Product Environmental Footprint (PEF) methods will improve how bio-based materials, chemicals and products are assessed and compared. This may be complemented by measures to improve bio-waste collection and valorisation, including through the upcoming Circular Economy Act, the production of biogas and biomethane, and the use of digestate as a bio-based fertiliser, through a Tripartite Agreement.

The Commission recalls that the importance of the ongoing major (EUR 2 billion joint funding) public-private initiative on Circular Bio-based Europe (CBE) Joint Undertaking (JU). Its ambition is to include sustainability and lowering the environmental footprint of the circular bio-based products and processes, based on bio-based feedstocks, such as sustainably sourced biomass, recycled waste and CO_2 captured from biogenic sources. The Commission aims to review the current CBE JU partnership arrangement, and identify the most effective and impactful future collaboration options under the next Multi-Annual Financial Framework.

In addition, the Commission agrees with the importance of ensuring the sustainability of biomass, and recalls the open calls under 2025 Horizon Europe work programme, aiming at filling this knowledge gap such as the projects selected under HORIZON-CL6-2025-01-ZEROPOLLUTION-02: Environmental impacts from the production of agricultural crops for bio-based industrial systems as well as the funded projects BioINSouth, and BIORADAR.

Paragraph 25: The current EU legislative frameworks applicable to food products derived from the use of biotechnology ensure high standards regarding the protection of consumer health, consumers' interest in relation to food and the environment for all types of food, in particular through the rigorous assessment of the most recent scientific data, for example on toxicity, allergenicity or environmental impacts. The Commission, based on the risk assessment carried out by EFSA will continue to ensure that only food products that have satisfactorily fulfilled all requirements regarding consumer and environmental safety and any additional requirement, including on aspects unrelated to safety can be placed on the EU market, in accordance with the respective legal frameworks. The Commission is committed to exploring various approaches to streamline and simplify the associated authorisation procedures without compromising the high safety standards in place (see above, paragraphs 8 and 10-12).

In addition, the R&I policy framework Food 2030, in its deployment under Horizon Europe, has taken into account social, ethical, economic, environmental and cultural aspects of food innovation, generating relevant knowledge and solutions.

Paragraphs 26 and 27: The Commission agrees with the need to address biosecurity risks, including bioethical considerations in conjunction with biotechnology and biomanufacturing innovation. The Commission welcomes the recognition of the biosecurity dimension in the context of advancing biotechnological and synthetic biology, and acknowledges the

emerging risk associated to technological advancements, targeting biosecurity in particular. Attention is warranted to ensure the responsible development, use and oversight of emerging technological capabilities, including the synthesis or functional modification of existing or newly engineered pathogens with attributes pertaining to epi- or pandemic potential. In this context, the Commission has proposed provisions in this sense in the Biotech Act I proposed in December. Furthermore, the Commission highlights that the Medical Countermeasures Strategy aims to reinforce preparedness for the next health emergency, irrespective of its origins. The Commission's assessment of health threats of both natural and intentional origin is regularly updated to take into account these new developments, e.g. by considering viruses of epidemic and pandemic concern which could be used to engineer biological threats. Furthermore, the Commission agrees with the report's emphasis on "EU strategic autonomy in biotechnology supply chains" and keeping "critical biomanufacturing inputs and expertise within Europe." Beyond this, and in line with the EU Life Sciences Strategy and the Medical Countermeasures Strategy, the Commission is aiming to strengthen the EU as a locus for life science and pharmaceutical research and development.

On 1 April 2025, the Commission adopted the new EU Internal Security Strategy Protect EU[4] in which it commits, as a key action, to present in 2026 a new Chemical, Biological Radiological and Nuclear (CBRN) Preparedness and Response Action Plan. To address the heightened risk of CBRN threats including the weaponisation of CBRN materials and bioterrorism, the new Action Plan will support Member States through dedicated training and exercises, and boost also their CBRN preparedness and response capabilities against all CBRN threats through innovative funding support as well as increased rescEU capacities and stockpiling of medical countermeasures.

As for bioterrorism and biorisks, the Commission is currently financing several research projects on medical countermeasures and exercises on CBRN first response. The Commission also conducts regular workshops on risks and scenarios of CBRN incidents, as well as medical countermeasure response. Moreover, the Commission is actively implementing its Health Security framework with the overarching Regulation (EU) 2022/2371 on serious cross-border threats to health[5], covering a broad range of serious cross-border threats to health, including those of biological, chemical and unknown origin.

Paragraph 28: Biotechnology is one of the identified critical technologies in the EU Economic Security Strategy for which the Commission is currently conducting a risk assessment with the aim of proposing mitigation measures along the pillars of 'promote', 'protect', and 'partner' to reduce dependencies and supply chain vulnerabilities for biotechnology and biomanufacturing. Under the 2023 European

[4] COM (2025)148 final.
[5] L_2022314EN.01002601.xml.

Economic Security Strategy, the Commission is therefore assessing particular sensitive biotechnologies to identify and monitor risks as regards supply chain risks but also risks related to the EU's access to these technologies as well as the risk of technology leakage. This work includes reaching out to industry and research stakeholders. The insights gained, including business secrets, are handled with due regard to confidentiality.

Paragraph 30: In its package for the next Multiannual Financial Framework (MFF), last July 16th, the Commission proposed a future European Competitiveness Fund aiming to consolidate 14 individual funding instruments from the current MFF in one framework to operate as an investment capacity to bolster European competitiveness in technologies and strategic sectors critical to EU competitiveness. The proposal foresees four policy windows including a 'Health, Biotech, Agriculture and Bioeconomy' one, reflecting strategic priorities, which are crucial to Union competitiveness and resilience.

To support the health biotechnology sector, the proposal aims to support specific objectives of contributing to the development and scalable production and uptake, availability and accessibility of medicinal products, medical devices, diagnostics and other medical countermeasures. To support bioeconomy policy, it will mobilise research and innovation funding, large-scale investment along the full value chain, including sustainable land management, and de-risk industrial deployment, bridging the gaps between research, innovation, and market upscale. In the meantime, programmes under the current MFF remain available to address the needs of the bioeconomy. These must be fully implemented, taking also into account the recommendations from the EIB Group, which include developing a bioeconomy booster programme, leveraging the Circular Bio-Based Europe Joint Undertaking (CBE-JU) flagship grant applications, and increasing flexibility in project support (e.g. high-risk investments in early-stage ventures[6]).

Paragraph 31: The Commission considers CERN as a pioneer amongst research infrastructures in anchoring an innovation ecosystem around its scientific activities. Through the 'IdeaSquare' the world-class scientific expertise of CERN is leveraged to support collaborative innovation. It is a 'proof of concept' of how research infrastructures can become centres of gravity for innovation ecosystems. The multiplication of such initiatives and their networking at the European level can significantly contribute to Europe's attractiveness for startups to be founded and to scale.

The European Strategy on Research and Technology Infrastructures strengthens the EU capacities supporting research, innovation and technology development through actions that aim to mobilise new

6 EIBG, Scaling up Europe's Bio-based industries, 2025

investments. It proposes concrete actions to improve the availability and accessibility of such infrastructures, in particular for innovative SMEs and startups. The Strategy addresses the whole ecosystem of research and technology infrastructures, benefiting also the biotechnology and biomanufacturing sector.

To accelerate the process from lab to market, the Startup and Scale up Strategy proposed a dedicated Lab to Unicorn initiative aimed at reinforcing networks of universities, and helping academic institutions, research performing organisations and inventors protect their Intellectual Property (IP) and launch spinoffs in all the sectors. These efforts are complemented by a dedicated action in the EU Life Sciences Strategy, which envision pilots for phased, stepwise funding of collaborative research under the 2026-2027 Horizon Europe work programme, leveraging results from past EU projects to accelerate the development of promising health technologies.

Moreover, the Strategic Framework for a Competitive and Sustainable EU Bioeconomy announced that biotechnology and biomanufacturing will also benefit from clearer and more consistent standards that support market uptake as the Commission will accelerate the development of bioeconomy standards and metrology. It will strengthen its investments under the current MFF in pre-normative activities by developing, testing and validating strategic pre-standards, including on data, in real-world setting.

Further, the Medical Countermeasures Strategy announced the development of a Medical Countermeasures Accelerator to support innovators throughout the development cycle, from research to market entry. Lastly, the Commission highlights that investments in infrastructure and long-term innovation frameworks are ongoing and continuing in the area of medical countermeasures. For instance, the European Vaccines Hub (EVH) for Pandemic Readiness funded by the Commission is a pan-European centre dedicated to advancing public-health–relevant vaccine development.

Paragraph 32: Research and innovation play a significant role in the industrial climate neutrality transition of energy-intensive and hard to abate industries. It supports the development and adoption of new energy efficient production processes and technologies enabling the switch from fossil fuels to renewable energy, e.g. via electrification related to hydrogen use or development of Carbon Capture and Utilisation technologies for hard to abate industrial CO_2 emissions. Energy-intensive process industries in one of the focus of the strategies and policies supported by EU Industrial research and innovation[7] and comprise sectors which are also linked to biomanufacturing processes, such as pulp and paper.

[7] Industrial research and innovation - European Commission.

The Commission welcomes the Parliament's position on the revised Renewable Energy Directive which will address easier permitting procedures. These procedures will also provide benefit for renewable energy projects as well as infrastructure projects.

In addition, with the Affordable Energy Action Plan, the Commission is launching an ambitious programme to support citizens, businesses and industry by driving growth and investment and promoting decarbonisation efforts with a focus on decreasing energy costs. In line with the Energy Taxation Directive, which allows decreasing taxes down to zero for energy consumed by energy intensive industries, the Commission will issue a recommendation to Member States on how to use such flexibilities and will ensure across all sectors that electricity is taxed less than other energy sources while pursuing our long-term decarbonisation objectives.

The Commission agrees on the need to ensure access to affordable energy for biotechnology and biomanufacturing operators and notes an open call under Horizon Europe Work Programme HORIZON-CL6-2025-01-CIRCBIO-11: Demonstration of reduced energy use and optimised flexible energy supply for industrial bio-based systems seeking to support the uptake of innovative low-energy bio-based processes and the use of renewable energy in the processes and utilities of the industrial assets.

Paragraph 33: The Commission agrees with the need to support the skilled and diverse European workforce in the biotechnology and biomanufacturing sectors and for the promotion of entrepreneurial skills, in close collaboration with industry and research institutions; the projects selected in the call under the CBE JU (Circular Bio-Based Europe Joint Undertaking) work programme 2025 (HORIZON-JU-CBE-2025-CSA-01 Develop and deploy new curricula and knowledge exchange practices relevant to bio-based systems), are expected to contribute to the curricula, related to skills' development for the sustainable bio-based systems and increased circularity, as well as to the deployment of EU-wide actions supporting the acquisition of new skills, as relevant for the sustainable and circular bio-based systems. As President Von Der Leyen highlighted during her landmark speech at La Sorbonne in May, world-class research infrastructures are a key pillar of 'Choose Europe'. Research infrastructures in the life sciences are excellently networked, offering a common catalogue of services and contributing to Europe being a premier destination for biotechnology researchers. Moreover, the upcoming 'European Strategy on Research and Technology infrastructures' foresees actions to ensure the long-term sustainability and cutting-edge capacities of world-class infrastructures, as well as new training opportunities for managerial and technical staff of infrastructures.

Paragraph 34: Startups and SMEs are pivotal in propelling innovation in life sciences yet face unique challenges in scaling up and accessing necessary resources. The Commission intends to fast-track life science innovations to market by establishing a dedicated Life Sciences Strategic Interface between investors, corporates and life science

startups. This flexible demand driven interface will also leverage the European Innovation Council's (EIC) portfolios and the EIC's Trusted Investors Network (TIN).

Through the expansion of the EIC, which will focus on challenge-driven, staged funding for high-risk innovations by introducing more ARPA-like processes[8], the Strategy will improve funding conditions for high risks SMEs in sectors like biotechnology and biomanufacturing. Also beneficial will be the announced launch of a Scaleup Europe Fund, aimed at bridging the financing gap of deep tech scaleup companies and mobilising institutional investors through the European Innovation Investment Pact. The work with corporates, improvement of procurement, reduction of regulatory fragmentation through the proposals 'EU Inc.' and the European Business Wallet will enhance cross-border investments. In addition to these, both the EU Life Sciences Strategy and the Startup and Scale up strategy envision dedicated measures to foster public procurement of innovative solutions, within the public sector, thereby creating new markets and driving demand for cutting-edge products and services developed by startups and SMEs.

The Medical Countermeasures Strategy further aims to support and boost investments in the medical countermeasures sector, including the biotechnologies and biomanufacturing industry, through various financing tools addressing market failures. Notably, through HERA Invest, innovative EU SMEs can receive financial support through loans to bridge the investment gap to develop medical countermeasures.

In the context of the upcoming revision of the EU public procurement directives and the upcoming European Innovation Act, the Commission will seek ways to improve and simplify the access to public procurement, taking into account the needs of startups and scaleups and increase total investments in public and private innovation procurement across the EU. The European Circular Bioeconomy Fund (ECBF) supports the scaling of bioeconomy start-up companies by leveraging public funding with private investment. Aimed at supporting the development of bioeconomy sectors in Europe, the ECBF has strong focus on ensuring positive sustainability impact. The ECBF is proving to be successful in supporting early-stage startups in the EU circular bio-based economy sector as well as ensuring meaningful sustainability performance impact (e.g. GHG emission reductions).

EU policy-backed financial instruments including those implemented by the EIB and EIF play a crucial role in accelerating the deployment of market-ready innovation.

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[8] ARPA (Advanced Research Projects Agency) is a U.S. government agency that funds high-risk, high-reward research to drive breakthrough innovations in science and technology, originally established as ARPA (now DARPA) under the Department of Defence and later replicated in other sectors like energy (ARPA-E) and health (ARPA-H).

These instruments are especially effective in closing the “valley of death” between R&D and commercialisation, a phase where many promising innovations struggle to scale. For example, venture debt facilities supported by InvestEU or Horizon Europe provide flexible financing for companies with strong growth prospects but limited collateral, allowing them to invest in talent, infrastructure, or international expansion without diluting ownership early on. This approach enhances the risk-return profile for investors, particularly in capital-intensive sectors like deep tech, clean tech, and digital health, which align with EU strategic autonomy and competitiveness objectives. It also complements national efforts by aligning EIF/EIB support with startup and scale-up ecosystems, including export credit schemes, innovation procurement, and SME equity platforms.

Paragraph 35: Public-private partnerships are essential for de-risking biotechnology and biomanufacturing innovation. The InvestEU programme supports sustainable investment, innovation and job creation in Europe, providing long-term funding by leveraging private and public funds and helping to mobilise and de-risk private investments for the EU's top policy priorities, including in the biotech and biomanufacturing sector. The InvestEU Fund is implemented through implementing partners that will invest in projects, benefitting from the protection of EU budget guarantee. The main partner is the EIB Group, and the EU guarantee is open also to national promotional banks and international financial institutions, such as the EBRD. The Startup and Scaleup Strategy underlines the importance of public-private partnerships and the role of the InvestEU, CBE JU or EIC work programmes. It also proposes expanding de-risking instruments and support mechanisms for biotech SMEs and scaleups. Overall, the Commission agrees that public-private partnerships are an important instrument for de-risking biotechnology and biomanufacturing innovation and for increasing the likelihood that IP and industrial capacity remain in Europe.

With regards to the next Multiannual Financial Framework (MFF) the Commission already provided some relevant information in the reply to paragraph 30.

Paragraph 36: The Commission identified the public acceptance as one of the eight challenges listed in the Biotechnology and Biomanufacturing Communication. To address this challenge a topic was included in the Horizon Europe work programme 2025 specifically on the use of different biotechnology applications for food and food ingredients. Furthermore, ongoing projects from Horizon Europe are also tackling this issue (e.g. project B-TRUST) and at least three innovation action topics, including flagships, address the social acceptance of the proposed bio-solution in the CBE JU work programme 2025. These topics have a total budget of EUR 48 million.

In addition, the EU Life Sciences Strategy considers that in order to foster public trust and the acceptance of technologies, citizens should understand how life sciences work and how technologies may improve people’s well-being. The Commission is proposing an action to mobilise

EUR 2 million financial support from the Horizon Europe work programme 2026-2027 to support life science stakeholders and policy makers in public outreach by setting up a repository of tools and best practices in responsible R&I, risk and science communication, and pilot public outreach measures.

Paragraph 37: The Commission fully agrees with the key role of the Horizon Europe Programme in boosting scientific research and innovation in the biotechnology area. The 2025 Horizon Europe work programme addressed several topics on bioeconomy and biotechnologies covering all the sectors, agriculture, food, feed, marine, industrial, health and environment and targeting research as well as innovation activities. In addition, at least three topics under the CBE JU work programme 2025 aim to contribute to the Commission Biotechnology and Biomanufacturing Communication by increasing the innovation and competitiveness of industrial biotechnology across different topics and by supporting the scaling up of biotech solutions and fostering the increase of biomanufacturing capacity at European level (IA-01: Sustainable macroalgae systems for innovative, added-value applications: cultivation and optimised production systems; IA-04: Cost-effective and robust continuous biotech bio-based processes and RIA-03: Alternative biomanufacturing routes for natural and synthetic rubber). FIBENOL, an Estonian company, received support from the CBE JU to construct a first-of-its-kind plant. Using biotechnology, this facility sustainably transforms wood residues into valuable compounds for use in construction, bio-based plastic materials, packaging, and other sectors.

Furthermore, the European Innovation Council (EIC) has funded projects under Horizon Europe framework programme for R&I 2021-2027 over EUR 625 million for biotechnology and biomanufacturing in areas including industrial biotechnology, agrifood biotech and healthcare biotechnology to support companies, in particular start-ups and SMEs to scale-up and deploy innovative products. The EIC Accelerator funded projects on agrifood biotech for around EUR 110 M. One example is the French company, Green Spot Technologies, which through a zero-waste process is able to leverage upcycling and fermentation at industrial scale to produce natural ingredients already commercialised with functional and nutritional advantages and the lowest environmental footprint. Another example is Solmeyea, a Greek start-up which unifies biotechnology and sustainability. They use white microalgae biomass to produce food and cosmetics ingredients which are commercially available on the EU market.

Looking ahead, the EU Life Sciences Strategy announces that the Commission will develop an action on a strategic R&I agenda on food systems. The aim will be to foster the development of competitive, sustainable and resilient food systems solutions, complementing the forthcoming strategic approach to R&I in agriculture, forestry and rural areas announced in the Vision for Agriculture and Food.

Paragraph 39, 40, 41: The Commission agrees with the need to integrate biotechnology and biomanufacturing innovation into the EU

digital and AI strategies and recalls that this integration was identified as a strategic priority in the Biotechnology and Biomanufacturing Communication, in the AI Continent Action Plan[9] and in the EU Life Sciences Strategy. The Commission highlights the significant ongoing investment to support the application of AI in biotechnology and biomanufacturing through the Horizon Europe and Digital Europe Programmes, for example the calls under the Horizon Europe 2025 Work Programme[10]. The social aspects are to be duly considered in this context and social innovation is encouraged, especially to address the societal concerns and perceptions on the role of AI in the bio-based innovation and broader bioeconomy (e.g., impacts on skills and job opportunities/risks). The Commission also underlines the investment in computing infrastructure, through the creation of the AI Factories, some of which will enable AI development for life sciences.

By fostering collaborations among biotech clusters and leveraging AI and data, the EU Life Sciences Strategy proposes actions to optimize the research and innovation ecosystem. Initiatives such as the European Life Sciences R&I Data Assembly, and targeted actions to develop and populate strategic biodata resources will further accelerate the biotech innovation pathways. In the area of AI, the Commission will continue investing in AI based applications and tools, including the integration of multi-modal generative AI technologies into multidisciplinary biomedical research (EUR 50M from Horizon Europe), boosting the European genomic data infrastructure (EUR 25M from Digital Europe Programme-DEP), use of AI as part of the establishment of the ICU (Intensive Care Units) Data Space (EUR 10M from DEP), and the emergence and adoption of the next generation of virtual human twins solutions (more than EUR 30M from DEP).

The Commission will further consider the strategic potential of AI-driven biotechnology biomanufacturing research and innovation in the European Strategy for AI in Science, which aims at accelerating the safe and responsible uptake of AI by European researchers. As announced in the AI Continent Action Plan, the Commission launched the Resource for AI Science in Europe (RAISE) to pool resources that push the technological boundaries of AI and tap into its potential to facilitate scientific breakthroughs in key disciplines. A pilot phase of RAISE has been launched 2026

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[9] COM(2025) 165 final.

[10] HORIZON-CL4-INDUSTRY-2025-01-DIGITAL-6: AI Foundation models in science (GenAI4EU); HORIZON-CL6-2025-01-CIRCBIO-09: Unleashing the potential and advancing the impact of the digitalization/Artificial Intelligence of the climate-neutral bio-based value chains, HORIZON-CL6-2025-01-CIRCBIO-08: Bioprospecting and optimized production of the terrestrial natural products: new opportunities for bio-based sectors, HORIZON-CL6-2025-01-CIRCBIO-14: Bioprospecting and optimised production of marine/aquatic natural products in the omics & artificial intelligence era).